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| APPLICATION NO.   | FILING DATE             | FIRST NAMED INVENTOR      | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------------------|---------------------------|---------------------|------------------|
| 10/738,473  | 12/17/2003              | Donald K. Jones           | CRD5061             | 8194             |
| 27777<br>PHILIP S. JOH                                      | 7590 03/16/2007<br>NSON | EXAMINER                  |                     |                  |
| JOHNSON & J   |                         | WILLIAMS, CATHERINE SERKE |                     |                  |
| ONE JOHNSON & JOHNSON PLAZA<br>NEW BRUNSWICK, NJ 08933-7003 |                         |                           | ART UNIT            | PAPER NUMBER     |
|   |                         |                           | 3763                |                  |
|   |                         |                           |                     | A                |
| SHORTENED STATUTOR  | Y PERIOD OF RESPONSE    | MAIL DATE                 | DELIVERY MODE       |                  |
| 3 MONTHS  |                         | 03/16/2007                | DADED               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|  |   | Application No.                     | Applicant(s)      |  |  |  |
|--|---|-------------------------------------|-------------------|--|--|--|
| Office Action Summary  |   | 10/738,473                          | JONES ET AL.      |  |  |  |
|  |   | Examiner                            | Art Unit          |  |  |  |
|  |   | Catherine S. Williams               | 3763              |  |  |  |
| Period fo  | The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply |                                     |                   |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                                     |                   |  |  |  |
| Status   |   |                                     |                   |  |  |  |
| 1) 又   | Responsive to communication(s) filed on 04 D  | ecember 2006.                       |                   |  |  |  |
| ·  | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.  |                                     |                   |  |  |  |
| 3)   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is       |                                     |                   |  |  |  |
|  | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.                             |                                     |                   |  |  |  |
| Dispositi  | on of Claims  |                                     |                   |  |  |  |
| 4)🖂  | 4)⊠ Claim(s) <u>1,3-14,16-19,21,23 and 26-29</u> is/are pending in the application.                                   |                                     |                   |  |  |  |
|  | 4a) Of the above claim(s) is/are withdrawn from consideration.  |                                     |                   |  |  |  |
| 5)🖂  | 5)⊠ Claim(s) <u>26,27 and 29</u> is/are allowed.  |                                     |                   |  |  |  |
| 6)⊠  | s)⊠ Claim(s) <u>1,3-14,16-19,21,23,28</u> is/are rejected.  |                                     |                   |  |  |  |
| 7)   | ) Claim(s) is/are objected to.  |                                     |                   |  |  |  |
| 8)□  | Claim(s) are subject to restriction and/o   | r election requirement.             |                   |  |  |  |
| Application Papers   |   |                                     |                   |  |  |  |
| 9)   | The specification is objected to by the Examine   | r.                                  |                   |  |  |  |
| 10)  | The drawing(s) filed on is/are: a) ☐ acc  | epted or b)□ objected to by the l   | Examiner.         |  |  |  |
|  | Applicant may not request that any objection to the   | drawing(s) be held in abeyance. See | e 37 CFR 1.85(a). |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |                                     |                   |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |                                     |                   |  |  |  |
| Priority u   | ınder 35 U.S.C. § 119   |                                     |                   |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:   |   |                                     |                   |  |  |  |
|  | 1. Certified copies of the priority documents have been received.   |                                     |                   |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |   |                                     |                   |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |   |                                     |                   |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |   |                                     |                   |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |                                     |                   |  |  |  |
|  |   |                                     |                   |  |  |  |
| Attachment(s)  1) Mileting of References Cited (RTO 902)  4) Union of References Cited (RTO 902)   |   |                                     |                   |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date   |   |                                     |                   |  |  |  |
| 3) 🔲 Inform  | nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date  | 5) Notice of Informal P 6) Other:   |                   |  |  |  |

## **DETAILED ACTION**

## Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/4/06 has been entered.

## Claim Objections

Claims 11 and 13 are objected to because of the following informalities: claim 11 is a duplicate of claims 10 and claim 13 is a duplicate of claim 12. Appropriate correction is required.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,3-7,10-14,16-19,21,23 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eder et al (USPN 5,980,550) in view of Chen et al (USPubN 2004/0029952). Eder discloses a vascular occlusive helically wound metallic embolic coil (202); a thrombus inducing bioactive agent integral coating (204); and an outer barrier coating applied to the

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bioactive agent (206). See figure 2 and 3:17,24-29,36-38 and 66-67. Eder fails to disclose an outer barrier that exhibits the characteristics of being substantially inert to bodily fluid but dissolving when exposed to an external fluid agent.

However, Chen discloses such an outer barrier coating. Chen teaches the use of ethylene vinyl alcohol (EVOH) as an outer coating on medical devices that acts as a diffusion barrier disposed over a coating layer carrying an active agent for reducing the rate that the agent is released. See paragraph 0013.

At the time of the invention, it would have been obvious by one skilled in the art to substitute the outer barrier of Eder with the outer barrier of EVOH as taught by Chen. The motivation is provided by Chen in that the EVOH provides a barrier that reduces the rate of release. One skilled in the art would understand that this barrier would lengthen the amount of time the bioactive agent of Eder is released thereby furthering an objective of the device of Eder.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eder in view of Chen. Eder in view of Chen meets the claim limitations as described above but fails to include the bioactive agent being polyglycolic acid.

However, at the time of the invention, it would have been obvious by one skilled in the art to incorporate polyglycolic acid as the bioactive agent into the invention of Eder in view of Chen. Applicant has not provided that polyglycolic acid versus other thrombic agents provides an advantage, is used for a particular purpose, or solves a problem. Furthermore, one skilled in the art would expect polyglycolic acid or the thrombus inducing agents of Eder to perform equally well.

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Allowable Subject Matter

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Claims 26-27 and 29 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Catherine S. Williams whose telephone number is 571/2724970.

The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Nicholas D. Lucchesi can be reached on 571/2724977. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

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like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catherine S. Williams

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March 6, 2007

CATHERINE S. WILLIAMS

PRIMARY EXAMINED